OPINION

Why institutional review boards should have a role in the open science movement

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Open science involves the use of practices across the research life cycle that facilitate the transparency, reproducibility, and availability of scientific products and output. Prominent open science practices include registration of study protocols and preanalysis plans; materials, data, and code sharing; and publication of summary findings in open access outlets (1). To achieve openness as the default approach, initiatives are trying to use a systems approach to engage stakeholders—namely, scientific journals, funding agencies,

Institutional review boards are overlooked, yet critical, stakeholders for the promotion of open science initiatives that enhance access to research products. Image credit: David Cutler (artist).

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and professional societies (2, 3). Proponents hope to realign the research enterprise with the values of transparency and reproducibility (4).

Institutional review boards (IRBs) are overlooked, yet critical, stakeholders for proponents to engage in open science initiatives (5). For instance, IRBs can require modifications to and even disapprove data sharing plans based on information in the application, protocol, and informed consent forms investigators submit for IRB review (6). Conversely, IRB workflows can increase if a greater number of submissions require higher levels of IRB review because of data sharing plans that risk disclosure of identifiable private information about living individuals. Practical tutorials on ethical open science primarily focus on educating study investigators about their responsibilities to protect human research subjects. IRBs, in turn, need to be informed about open science practices and the impact of their growth on IRB responsibilities to protect human research subjects. In other words, IRB members and professionals themselves should be part of the movement toward open science.

Although IRBs are ethics bodies concerned with moral obligations (7), they are best understood through a regulatory lens: that is, IRBs are principally compliance offices responsible for ensuring that an institution's federally funded human-subject research is compliant with specific federal regulations. Institutions can assign additional responsibilities to their IRBs; yet even in these instances, the federal regulations strongly influence (if not determine) IRB operations for human-subject research at an institution (6). Furthermore, the open science movement is gaining traction alongside historic regulatory changes that have privacy, confidentiality, and reduction of IRB overreach and administrative burdens as core goals (8). Consequently, IRBs likely will be resistant to open science reform efforts—including those based on ethically sound arguments—that risk breaches of privacy and confidentiality, IRB overreach, or unnecessary burdens on IRB administration.

First and foremost, IRB functions and operations that aim to enable open scientific research must avoid noncompliance with the Common Rule (45 CFR 46), the US federal regulations for the protection of human subjects in research. The regulations most relevant to open science are concerned with minimizing the risk of harm resulting from breaches in the privacy of subjects and confidentiality of data. These regulations are also a top priority for IRBs, and the recent revisions of the Common Rule explicitly note that advances in data matching and reidentification exacerbate risks of breaches of privacy and confidentiality (8). The result is a tension between the undeniable role that IRBs have in mitigating the risk of these breaches and the mounting expectations for investigators to apply practices (particularly data, code, and materials sharing) that increase the probability of this same risk.

In light of the above, investigators who plan to use open science practices would benefit from IRB procedures, guidance, templates, and expertise that can clarify how to practice open science while remaining compliant with the Common Rule. For example, study proposal forms and submission systems could include a specific field for each open science practice so that IRBs could systematically collect this information from investigators in their review of research. To assist investigators who are developing proposals, IRBs should create written guidance explaining how open science practices can escalate the level of IRB review and potentially prevent IRB approval. At a minimum, this guidance should address definitions of identifiable private information and biospecimens (§46.102(e)(5) and (6)); analytic technologies or techniques that generate identifiable private information and biospecimen (§46.102(e)(7)(ii)); exemption categories with criteria on the identifiability of subjects (§46.104(d)(2)–(4)); and adequate procedures for protecting the privacy of subjects and maintaining confidentiality of data (§46.111(a)(7)).

In addition, IRBs should provide templates of informed and broad consent forms with approved language on data, code, and materials sharing—especially statements about the confidentiality of records and future research use (§46.116). To fill in the gaps, IRBs can invite experts in open science practices, data matching, and reidentification as members (§46.107(a)) or consultants who assist in study review on a case-by-case basis for issues requiring expertise not available on the IRB (§46.107(e)).

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Second, IRB enablement of open scientific research should be consistent with the ethical principles detailed in the Belmont Report. Published in 1979 by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, the Belmont Report identifies the ethical principles and guidelines for the protection of human subjects of research. These principles serve as a foundation for—and provide an analytical framework to guide—the resolution of ethical issues in human subject research that are not explicitly covered by the specific regulations in the Common Rule. Several regulations discussed above entail "respect for persons" (informed consent offering subjects the opportunity to choose what will happen to their data) and "beneficence" (assessing risks that may occur from privacy and confidentiality breaches) that might constrain the use of open science practices.

However, when findings are not made public or other products of research not shared, the subsequent loss of generalizable knowledge from research also entails a violation of these principles (7), especially to those who chose to participate in research because they want to contribute to the furthering of knowledge. Consequently, the ethical

principles of the Belmont Report also suggest that IRBs actually have a responsibility to support open science practices.

Lastly, research organizations that directly influence IRBs could help refine and clarify the role of IRBs in the movement toward open science. In the United States, the Office for Human Research Protections (OHRP) is responsible for ensuring that human subject protection regulations are appropriately and effectively applied to the changing needs of the research community, such as those caused by the movement toward a research enterprise "open by design" (2). Consequently, OHRP could create guidance that helps IRBs establish policies and procedures that enable transparent human subject research in compliance with regulations. The Association for the Accreditation of Human Research Protection Programs (AAHRPP) and Public Responsibility in Medicine and Research (PRIM&R) could then incorporate this guidance into their accreditation programs for institutions and certification programs for IRB professionals. In particular, these groups could adjudicate provocative proposals, such as requiring investigators to register studies prior to IRB approval and checking that investigators have shared results before closing continuing review (7).

In summary, initiatives focused on integrating open science into the research enterprise should engage IRBs in these endeavors. In addition to ensuring compliance with Common Rule regulations, IRBs can assist open science proponents in navigating other federal regulations for protecting human subjects in specific contexts (e.g., US Food and Drug Administration and Health Insurance Portability and Accountability Act requirements), regulations at other levels of governance (international, state, local, and tribal), and supplemental mandates for IRB operations made by their host institutions. Including IRBs in the movement toward open science will not only facilitate the "contribution of open science to producing better science" (4) but also maintain continued public trust in the research enterprise by protecting its most important stakeholders: the members of the public who participate in research.

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